

PTO/SB/08A (08-03)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Art Unit	1614
		Examiner Name	Not yet assigned
Sheet 2 of 2	Attorney Docket Number	141-424	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
MF	DN	ABDALLA ET AL, Preparation and evaluation of Metformin Hydrochloride Controlled-Release Tablets, STP Pharma 4(1) pp. 15-20, 1988.	

Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>		<b>Complete if Known</b>	
Sheet	1	of	5
		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Art Unit	
		Examiner Name	
		Attorney Docket Number	141-424

U.S. PATENT DOCUMENTS					
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
MF	AA	us- 3,174,901	03-23-1965	Sterne	
	AB	us-3,960,949	06-01-1976	Ahrens et al.	
	AC	us-4,166,800	09-04-1979	Fong	
	AD	us-4,389,330	06-21-1983	Tice et al.	
	AE	us-4,687,777	08-18-1987	Meguro et al.	
	AF	us- 4,839,177	06-13-1989	Colombo et al.	
	AG	us- 4,891,223	01-02-1990	Ambegaonkar et al.	
	AH	us- 4,968,507	11-06-1990	Zentner et al.	
	AI	us- 5,294,770	03-15-1994	Riddle et al.	
	AJ	us- 5,356,913	10-18-1994	Colca	
	AK	us- 5,376,771	12-27-1994	Roy	
	AL	us- 5,478,852	12-26-1995	Olefsky et al.	
	AM	us- 5,602,133	02-11-1997	Antonucci et al.	
	AN	us- 5,658,474	08-19-1997	Geerke	
	AO	us- 5,681,584	10-28-1997	Savastano et al.	
	AP	us- 5,698,220	12-16-1997	Cardinal et al.	
	AO	us- 5,719,188	02-17-1998	Colca	
	AR	us- 5,859,037	01-12-1999	Whitcomb	
	AS	us- 5,916,584	06-29-1999	O'Donoghue et al.	
	AT	us- 5,952,356	09-14-1999	Ikeda et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				

Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006
-----------------------	-------------------	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 5

**Complete if Known**

Application Number	10/664,803
Filing Date	September 19, 2003
First Named Inventor	Unchalee Kositprapa
Art Unit	
Examiner Name	
Attorney Docket Number	141-424

**U.S. PATENT DOCUMENTS**

Examiner Initials <sup>2</sup>	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>3</sup> (if known)			
MF	AU	us-5,955,106		09-21-1999	Moeckel et al.	
	AV	us-6,011,049		01-04-2000	Whitcomb	
	AW	us-6,031,004		02-29-2000	Timmins et al.	
	AX	us-6,099,859		08-08-2000	Cheng et al.	
	AY	us-6,153,632		11-28-2000	Rieveley	
	AZ	us-6,191,162		02-20-2001	Byrd et al.	
	BA	us-6,248,363		06-19-2001	Patel et al.	
	BB	us-6,291,495		09-18-2001	Rieveley	
	BC	us-6,296,874		10-02-2001	Cutie et al.	
	BD	us-6,329,403		12-11-2001	Odaka et al.	
	BE	us-6,383,471		05-07-2002	Chen et al.	
	BF	us-6,403,121		06-11-2002	Adjei et al.	
	BG	us-2002/0071866		06-13-2002	Geerke	
	BH	us-6,451,342		09-17-2002	Adjei et al.	
	BI	us-6,475,521		11-05-2002	Timmins et al.	
	BJ	us-6,524,621		02-25-2003	Adjei et al.	
	BK	us-2003/0113371		06-19-2003	Dhawan et al.	
	BL	us-2003/0118647		06-26-2003	Seth	
	BM	us-2003/0118649		06-26-2003	Gao et al.	
MF	BN	us-6,599,284		07-29-2003	Faour	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials <sup>2</sup>	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
MF	CA	WO	96/09823	04-04-1996	Luo et al.		
	CB	WO	98/11879	03-26-1998	Shell et al.		
	CC	WO	98/55107	12-10-1998	Shell et al.		
	CD	WO	99/47128	09-23-1999	Timmins et al.		
	CE	WO	99/55320	11-04-1999	Nishii et al.		
	CF	WO	00/28989	05-25-2000	Lewis et al.		
	CG	WO	00/72827	12-07-2000	Straub et al.		
	CH	WO	01/35940	05-25-2001	Lewis et al.		
	CI	WO	01/35941	05-25-2001	Lilliot et al.		
MF	CJ	WO	01/82875	11-08-2001	Cutie et al.		

Examiner  
Signature

/Marc Fitzgerald/

Date  
Considered

11/06/2006

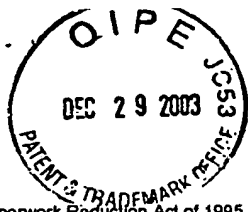
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

**English language translation is attached.**

**Business Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**



PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Completion if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Group Art Unit	
		Examiner Name	
Sheet 4	of 5	Attorney Docket Number	141-424

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
MF	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
	DB	P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving-tablet, and three sustained-release-products", Vol. 24, No. 4 - 1986, pp. 213-220.	
	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation	
	DD	O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
	DF	Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
	DG	National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
MF	DH	The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/664,803
		Filing Date	September 19, 2003
		First Named Inventor	Unchalee Kositprapa
		Group Art Unit	
		Examiner Name	
Sheet 5	of 5	Attorney Docket Number	141-424

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>2</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
MF	DI	Product Labeling for Glucophage® XR (July 2002).	
	DJ	ADA Professional Section Member Supplement 047 and 0503-506 (Poster) p. A110; A117	
	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
	DM	Rote Liste No. 11081 the Medicament Mediabet of MEDICE, Chem.-Pharm. Fabrik Pütter GmbH & Co. KG, Kuhlweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	
MF			

Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006
-----------------------	-------------------	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.